#### INTRODUCTION TO AUDITING

Although many people use the word audit, it is not always applied in a consistent manner. This is because people use words based on their previous experiences or what they have read. We have quality auditors, financial auditors, safety auditors, and tax auditors. All of these auditing schemes can be divided into two categories: compliance and management. A compliance audit looks for conformance to a set of rules. Examples of compliance audits include tax audits, financial audits, and regulatory audits. Compliance audits are designed to give assurance that activities have been performed properly. By their very nature, they are reactive not proactive. A management audit looks for both conformance with a set of rules and the effectiveness of those rules in achieving and organization's goals. Examples of management audits include quality audits, environmental, safety, and health audits, operational audits and government program audits.

The American Society for Quality has defined an audit as a planned, independent, and documented assessment to determine whether agreed upon requirements are being met. The international auditing standard, ISO 10011 (Guidelines for Auditing Quality Systems) defines quality audit as a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. Contained in the definition of the quality audit are two important concepts: compliance with written requirements and effectiveness of those requirements in meeting basic management controls. Auditing may be thought of as comparing reality with requirements.

This comparison process can be accomplished by three different sets of auditors and auditees: first party, second party, and third party. The first party audit, also known as an internal audit, is performed within your own company or organization. It is an audit performed within and organization to measure its own performance, strengths, and weaknesses against its own established procedures and systems. This can be a central office group auditing one of the plants, auditing within a division, local audits within a plant, or any number of similar combinations. There are no external customer-supplier audit relationships here, just internal customers and suppliers. The second party audit is performed by a customer on a supplier. They are also called external audits. A third party audit is performed by someone other than the customer, on the company itself, on a supplier, or regulated entity. The party to be audited will hire someone to audit them. The most common type of third party audit is an ISO 9000 registration audit. The third party conducting the ISO audit would be a registering body. In the U.S. the Registrar Accreditation Board (RAB) has established represented sources for conducting these audits.

The purpose of quality auditing is to examine the effectiveness of management directed control programs that are designed to maximize the quality of goods or services delivered to the customer. The philosophy of quality assurance programs is based on prevention rather than detection of problems. Quality auditing provides management with objective feedback based on facts, enabling management to make informed decisions.

### TYPES OF AUDITS

Quality auditing is concerned with three general types of audits. The system audit, the process audit and the product audit.

A quality system audit is a documented activity performed in accordance with written procedures or checklists to verify by examination and evaluation of objective evidence, that applicable elements of the quality assurance program have been developed, documented, and effectively implemented in accordance with specified requirements. Management uses the results of quality system audits to determine the degree to which company organizations meet commitments established by management and how effective the program is in assuring quality.

A process audit is verification by evaluation of a manufacturing or test operation against documented instructions and standards, to measure conformance to these standards and the effectiveness of the instructions. Such an audit is a check of conformance of process, personnel and equipment to defined requirements such as time, temperature, pressure, composition, amperage, component mixture, etc. It may involve special processes such as heat-treating, soldering, plating, encapsulation, welding, and nondestructive examination. This is a check for adequacy and effectiveness of the process controls over the equipment and operators as established by procedures, work instructions, and process specifications.

A product audit is the examination, inspection or test of a product that has been previously accepted for the characteristics being audited. Such an audit is a re-inspection and retest of the product that has already been accepted or a review of documented evidence of acceptance. It includes performing operational tests to the same requirements used by manufacturing, using the same production test procedure, methods, and equipment. The audit will measure the level of product conformance to specified standards of workmanship, performance, and quality. It is an indicator of quality going to the customer, and should be conducted from the customer's point of view. The audit frequently includes an evaluation of packaging; examination for cosmetics; check for proper documentation and accessories such as proper tags, stamps, shipment preparation, and protection. The audit may involve a check of accuracy of the tests, test equipment, and test procedure.

A quality system survey is an activity similar to a quality system audit but has a different purpose. A quality system survey takes place with relation to a prospective procurement of a service or an item. Generally, they are conducted prior to contract award and are used to evaluate the overall capability of a prospective supplier/contractor including the adequacy and implementation of his quality assurance program. In government procurement we refer to a quality system survey as a Pre-Award Survey (PAS). Pre-Award surveys are covered in more detail later in PQM 101.

#### PHASES OF THE AUDIT PROCESS

Auditing may be divided into three phases:

- planning and preparation phase;
- performance phase; and
- report and follow up phase.

The planning and preparation phase starts from the decision to conduct an audit. It includes all activities from team selection up to the on-site gathering of information. The performance phase begins with the on-site opening meeting and includes the gathering of information and analysis of that information. Normally, this is accomplished by conducting interviews, watching activities, and examining items and records. The report and follow up phase covers the translation of the audit team's conclusions into a tangible product. It includes the exit meeting with managers and publication of the formal report. The follow up deals with the actions resulting from the report and the recording of the entire effort. For audits resulting in the identification of weakness, the closure phase includes tracking and evaluating the follow up action taken by others to fix the problem and keep it from recurring.

## Planning and Preparation Phase

Between the time you receive an assignment and the time the audit start, there are many things to be done to lay the foundation and properly organize the work. Use the following nine steps in audit preparations:

- 1. Define the purpose of the audit. What do you and your customers want to achieve with the audit?
- 2. Define the scope of the audit. It establishes your boundaries and identifies the items, groups, and activities to be examined. It also helps to make the most efficient use of resources.
- 3. Determine the audit team resources. Auditors need to be qualified in the process they are auditing and independent from the organization being audited.
- 4. Identify the authority for the audit. One reason for identifying this authority is to defuse the natural human reaction to become defensive when informed of a forthcoming audit.
- 5. Identify the performance standards to use. Obtain copies of the various performance standards to be examined. List them in the audit plan.
- 6. Develop a technical understanding of the processes to be audited. You cannot perform an audit successfully unless you have a technical understanding of the processes you will be auditing. The best way to become knowledgeable in the process is to flow chart the process.
- 7. Contact those to be audited. Provide formal notification in writing to the organization being audited.
- 8. Perform an initial evaluation of lower tier documents to higher level requirements. This can be done as a desk audit and serves two purposes:
- a. to determine whether lower-level documents adequately respond to identified requirements of their higher-level performance standards.

- b. to obtain a better understanding of the program activity so that the performance phase of the audit can be completed in an efficient and effective manner.
- 9. Develop written checklists of the data needs. This will allow thorough coverage of the scope of the audit, help keep the audit on schedule and use the audit time efficiently. There are five types of data:
- a. <u>Physical properties</u>. Physical properties are measurements, inspections, or counts of tangible items. This type of data is perhaps the most reliable type of audit evidence.
- b. <u>Information from your senses</u>. Information from your senses provides many opportunities to evaluate an action as it is performed. By using your senses, you base your report on the actual performance of audited activities rather than just the paperwork.
- c. <u>Documents and records.</u> Documents and records are one of the most frequently used sources of data. Documents are used to specify action, while records are used to substantiate that something was performed, and that it met requirements.
- d. <u>Interviews.</u> This is the process of obtaining information from another person in response to your questions.
- e. <u>Patterns.</u> Comparison and relationships among data points may be used as a means of isolating or highlighting certain activities. Examples of patterns include trend analysis, percentages, and ratios.

## Performance Phase

The performance phase is the data gathering portion of the audit and covers the time period from arrival at the audit location up to, but not including the exit meeting. It consists of the following activities:

- Meeting with the auditee.
- Understanding the process and systems controls.
- Verifying these controls work.
- Communicating among team members.
- Communicating with the auditee.

All audits must have some sort of opening meeting. This starts the data-gathering phase of the audit. The opening meeting, sometimes called an entrance meeting, is held soon after your arrival at the audit site. You should have the entire team at the meeting, so that they may be introduced. Several things should be accomplished in the opening meeting. First, restate the purpose and scope so that the auditee totally understands. The most important part of the entrance meeting is to set the detailed schedule. It affects all the effort to come and allows the audit to proceed efficiently.

The data gathering process normally takes most of the time and effort in the performance phase of the audit. The job of the auditor is to gather facts, compare these facts to requirements,

and report the results to management. The checklist prepared earlier is the repository of these facts. It is a place to record the five types of data mentioned earlier in this text. Also remember to answer the fundamental questions of an audit:

- Do controls exist and are they adequate?
- Are controls are being implemented?
- Do the controls really work?

Preparing for the audit will begin to answer the first of these questions, but you need tangible proof that your conclusions are credible. The best way to obtain this proof is by examination of the product, which is the output of the organization your are auditing. Regardless of the activity being audited, you must find a way to tie your conclusions back to something tangible. The easiest way to accomplish this tie-in is through tracing. Tracing is a common means of collecting objective evidence during an audit. It can involve almost every facet of the system being examined and will result in a well-defined picture of actual practices. To trace means to follow the progress of something as it is processed. The mechanics of tracing are relatively simple:

- 1. Start either at the beginning, middle, or the end of the process.
- 2. Choose an action.
- 3. Gather information on the six process-affects (methods, machinery, material, manpower, measurement, and environment) for that action.
- 4. Follow the path of the transaction backward or forward through the process.

A good auditor possesses skill, training, and personal attitudes of a special nature. Part of this magical quality is the ability to conduct useful interviews. The interview process can be broken down into six steps:

- 1. Put the person at ease.
- 2. Explain your purpose.
- 3. Find out what they are doing.
- 4. Analyze what they are doing.
- 5. Make a tentative conclusion.
- 6. Explain your next step.

Interviewing is the process of obtaining information from another person in response to your questions. It is the most important form of data you can gather in auditing. It is also very difficult to do. The problem with trying to communicate with anyone is that different individuals will often receive significantly different messages from hearing the same words from the same speaker. Typically only about one third of the intended message is actually received by any one listener, a second third is garbled, and the remaining third not even heard! Just to make matters worse, different listeners will actually receive different parts of the total message.

There are certain basic problems in establishing communication with either a single individual or a group of individuals. Ensuring that the listener hears what is being said is the first big problem. The ability to hear the speaker may be impaired by physical barriers, noise, disinterest on behalf of the listener, lack of concentration, tiredness, or maybe even an undeclared deafness on the part of the listener. There could also be a problem caused by plain, old-fashioned boredom. The next problem is that the listener may hear well enough, but totally fail to understand what is being said. Understanding the received message is a complex business which can greatly be influenced by such issues as an individual's technical knowledge, the vocabulary used (which may be peculiar to that industry or service sector), the degree of familiarity with the spoken language, comfort with regional accents, and basic education. Messages need to be framed in the language and vocabulary of the target audience, not necessarily that of the speaker. The third significant problem to overcome is that of acceptance by the listener, the degree to which he or she is prepared to accept what they are being told. This is strongly influenced by the listener's attitude towards the speaker, the listener's situation, and personal prejudices.

The auditor's job would seem to be to go around asking questions. The real job of the auditor is to be a good listener. The information that is required may be stimulated by questions, but it is collected from the answers. The skill with which questions are asked will dictate the type of response that is received. Communication is made easier when properly structured, so it is important to ensure that the thought processes behind the questions are properly organized into subject categories and information flow patterns. Having taken this basic precaution, questions must be carefully structured to ensure that the relevant information is properly accessed.

There are five fundamental question types, and the selection of the type of question to ask is where the skill of the auditor will show. The question types are open questions, closed questions, clarifying questions, leading questions, and antagonistic questions. They all have their place in the interviewer's repertoire, and the careful use of the right type of question at the right point during the interview will extract the maximum amount of information from the interviewee in the shortest possible time. Even the antagonistic question has its place; handled very carefully it can be a useful backup device!

Open questions are those which cannot be answered by a simple yes or no. They require that the interviewee provide additional information to the questioner. They are used to obtain wide ranging answers, sometimes requiring a reply that can last for several minutes. Typical use is when asking for an explanation of how something is done, or seeking an opinion or determining the reason behind an action. Open questions enable the auditor to be passive while obtaining information; gaining explanations of information already gathered but unclear; let the auditee talk about subjects close to them with which they are comfortable, thereby making them relax and feel at ease with the questioner. The very nature of open questions leaves the initiative with the subject, and it is not difficult to end up with the conversation taking off down some related but tangential path to the one chosen by the auditor. Such tangents can provide useful additional information; they can also waste a lot of time! Should this start to happen, the auditor must gently but firmly bring the conversation back to the topic in hand. Examples of some typical open questions are:

- What is your job in the organization?
- What corrective action do you take when this happens?
- When are the audit report summaries issued?
- Where are these operations defined?
- Why were those AQLs/verification levels chosen?
- How do you determine the level of contaminant?

Closed questions are the reverse of open questions. They will typically require only a yes or no answer, or at the most, very few words. The problem with closed questions is that too much use of this technique can produce an effect that is rather like a hostile interrogation. Therefore, use in moderation. The uses of closed questions are to obtain specific information, to ensure that the auditee fully understands the question being asked, to probe a specific problem to uncover its cause, or to focus and guide the discussion down a certain route. Examples of closed questions are:

- When is that micrometer next due for calibration?
- Do you use a checklist for this operation?
- Has that batch been tested?
- What issue of the procedure do you have?

Clarifying questions are a mixture between open and closed question. They can be used with the objective of obtaining more information about a specific topic, or simply to ensure that the answer given by the auditee has been received and decoded correctly by the auditor. The aim is either to encourage the subject to provide more details by talking and elaborating upon the information they have already given or demonstrate that they are being heard and understood. The use of these questions can ensure understanding, eliminate ambiguity, and obtain further information. With a nervous interviewee these questions can also have a calming effect as the auditor demonstrates that he or she has been listening carefully and absorbing what has been said accurately. Many people are very nervous about being audited. It can often help for the auditor to use clarifying questions to demonstrate that he or she is really on the auditee's side. There are disadvantages here, too. Ask too many clarifying questions and the subject will begin to wonder why he or she is not getting through to the auditor. Examples of clarifying questions are:

- Can you explain what you mean by that?
- Would you talk me through those specific points?
- Just to confirm I have understood, that means....

A leading question is actually designed to suggest the expected answer to the subject. They may be great for solving TV crimes in front of judge and jury, but they are a lousy auditing technique, and they should be carefully avoided. The leading question obviously biases the information that is received in response. To determine if a question is leading the subject, consider if the question itself anticipates the answer. For example:

- Do you always take a 13 sample with this batch size?
- Is it routine to check that the calibration is valid before use?

The information required would be obtained more accurately by asking:

- How big a sample does this batch size require?
- What checks are carried out before starting to use this equipment?

If the interviewee perceives that he or she is under attack, the natural response is to go on the defensive. This results in limited responses at best and at worst, untrue responses. Antagonistic questions are those that arouse emotions in the audit because of the way that they are phrased, and the manner in which they are asked. There is a place for questions that challenge the interviewee to expand on the first answer given to an open question, but it must be done in a very careful and gentle manner to encourage further clarification or elicit evidence of the veracity of the answer given. As such, the use of the clarifying question is usually more effective. For example, the question "Why does this department never complete corrective action reports on time?" can be interpreted as direct criticism of the department head or the efficiency of the department. It will probably produce a negative or defensive response along the lines of "We've only been late with three in the last six months". The softer question would be, "What difficulties does this department experience when completing corrective action reports?" This will more likely result in an honest and frank review of the true situation.

The sixth technique in the auditor's armory is silence. Most people are very uncomfortable with silence. If the response to an open question leaves an interviewer with a strong idea that there is more waiting to be said, but no follow-up question immediately comes to mind, just remain silent, looking at the interviewee with an expression that says you are waiting for more. Almost invariably the interviewee will become uncomfortable and start to talk again. This technique can be used to draw information out of people, but again it has to be handled carefully. The interviewer has to be fairly confident that there is more to come, otherwise there is always the possibility that the auditee will assume that the conversation is over, get up and go away.

The meaning of a straightforward statement can be altered totally by the tone of voice and the stress on words. Take the statement, "Who authorized that?" This is a simple request for information. But by changing the stress placed upon a particular word in the sentence, the sense of the question can be completely changed. Thus the question, "Who authorized that?" implies "Who in their right mind would authorize that load of rubbish?" Asking "Who authorized that?" suggests that whoever it was hadn't the authority. Emphasis on the middle word, asking "Who authorized that?" implies that whoever it was shouldn't have done so whoever they are.

In each case the emphasis made the question antagonistic, and thus could cause people to go on the defensive. This is obviously not conducive to them freely providing information. Think carefully about emphasis on words when asking questions - such matters frequently influence the sense of what is heard.

There is little point in the auditor perfecting questioning techniques if he or she is not going to listen to the answers received; remember the balance required. Listening and questioning should be split 80/20. Few people can listen while they are talking. Neither is it possible to listen effectively when busy writing down notes. If there is a need to make a note, it should be either very brief, or made during a pause in the conversation, with a brief comment to the interviewee to pause a moment while the note is made.

While being an active listener, first, give the subject full undivided attention, in an environment that has minimal noise or other distractions. Second, make sure that the interviewee knows that he or she is being listened to by acknowledging the information with eye contact, nods, a smile when appropriate, or occasionally a verbal acknowledgement such as "yes", "I see", or "OK". Try to keep such acknowledgements to a minimum as it interrupts the flow, and many people find it intensely irritating. The interviewee will also recognize that he or she has attention if the occasional follow up question is put, to clarify something or take the interview on to the next stage. The important things to avoid are anticipating an answer and interrupting the speaker with the rest of the information, selectively listening and only hearing that which confirms a preconceived idea and switching off during a long and imprecise answer. Don't doodle, look out the window, watch the people walking by, or go to sleep. An important courtesy to remember is to always ask permission to make notes during the conversation. Do it in such a way that permission cannot be refused!

# Audit Reporting and Follow up

The audit report is your final product. Regardless of the source or purpose, it is generally accepted that reports should have accuracy, conciseness, clarity, timeliness, and tone. The report must be completely factual, in that every statement and reference must be based on one of the five forms of data previously discussed. It must be concise so that superfluous words do not block reception of the message. This goes right to the issue of clarity, the ability to put your thoughts into the mind of the reader. If your report is not issued in a timely fashion, the facts will have been forgotten and other crises will have taken the attention of your audience. Finally the tone of the report must be courteous and professional.

In addition to these traits, which are common to all reports, your report needs to possess the additional characteristics of relevance, consistency, comparability, and should be verifiable. Unless your report is relevant to the business needs of your customers, it will be ignored. Consistency of reports over the year is desirable to show trends and provide for greater comprehension by the reader. After they are familiar with the format and contents, they know where to look for desired information. Reports from a number of auditors should be comparable to allow for maximum efficiency and fairness. Finally, your reports should be verifiable. The auditee may not always be able to verify them personally, since we cannot track down the evidence for every piece of history known. But if you use generally accepted names for things (i.e. foot, yard, milling machine, and batch preparation files) there is relatively little danger of your message being misunderstood. When you refer to specific items or locations at the audit

site, the perception of verifiability is enhanced. One of the main purposes of a structured checklist is to record supporting information. However putting checklist-like detail in the report makes it too cumbersome and unreadable. Your completed checklist should be kept in the office file as a backup. It should not be included in the report.

The report should also include a findings statement or positive practice statement. A finding is an audit conclusion that identifies a condition having a significant adverse effect on the quality of the activity under review. Findings are serious problems that usually point to deficiencies in management control systems. They should be supported by observations that are objective evidence (facts) which attest to incidence of non-compliance or non-conformance. Reports should generally be limited to six or fewer findings. We know that a small percentage of certain characteristics will account for a high percentage of certain problems. For audits this means the vital few problems will make the major contribution to the lack of quality in most organizations.

The audit report should not include recommendations. When the audit group starts to provide solutions to another organizations management control problems, the inevitable result is a decrease in quality of the product or service. There are several reasons for this. The receiving organization often does not know what you really mean in a suggestion and may be angry with you for making it in the first place. So they do an obviously stupid thing just to show you how far off base you are. Problems by their very nature are often difficult to solve. At times, this may require a very extensive analysis or an in-depth investigation. In the limited time for an audit, the team cannot always devote the resources necessary to find the underlying root causes to a difficult problem, so the solution is inadequate. Don't be tempted to suggest some meaningless approaches for solving the problem, when you don't have enough information. You may attempt to suggest or recommend a solution based upon your prior experience in a similar situation. But because your solution was not "invented here", it becomes suspect and you stand a chance of being accused of bias. If you allow yourself to recommend, suggest, or direct the necessary corrective action, then you have assumed at least partial ownership of the problem, with little or no resources to correct it. This not an ideal position to be in. Ownership of the quality of product or service is no longer clearly defined because you have taken some of the ownership away. When you take away ownership you remove responsibility and accountability.

The report will contain an overall summary statement of everything you have examined. The summary is the most important part of your entire report. It should include good news as well as the bad. Usually, a one-paragraph, general discussion of the overall program controls is sufficient. There should one or two short sentence statements of each of the findings.

The summary section should answer these questions:

- Are necessary controls present?
- Are they implemented across all activities?
- Do they work?
- Is the group achieving those higher level controls

The exit meeting is the first formal opportunity for you to present your report to the audited organization's managers. The exit meeting is the job of the team leader. The team leader should retain control of this meeting and not engage in any discussion or argument over the conclusions of the audit. Give a short recap of the audit scope and purpose, and then get right into the summary followed by review of the findings with requests for corrective action. Once the re-cap of the audit report has been given and the copies distributed thank the organization for their time and leave immediately.

The follow-up part of this phase starts after the formal report is issued. It involves the following activities:

- Evaluation of the response
- Verification of the response
- Closing of the audit
- Assembly of the records

After the audit report is issued, a response is requested from the auditee if any adverse findings were presented. This response is not to report that all problems have been fixed; rather, it sets forth the action to be taken. The response should be evaluated for adequacy. You are looking for:

- Identification of the underlying cause of the condition
- Plans for fixing the specific deficiencies, listed as facts under the finding statements
- Plans for fixing the underlying cause
- Due dates for accomplishing the corrections

Once the response has been analyzed and found to be acceptable, corrective action must be verified in some fashion. Several options are available to you.

- 1. The response adequately describes the conditions of change and there is reasonable chance of success. Accept the response and close out that finding immediately.
- 2. Some changes involve new or revised documents. Request that the organization forward any changed documents to you once issued. Provided that the changed documents meet the requirements, the finding may be closed.
- 3. It may be necessary for someone from your organization to perform a brief follow-up visit to personally verify the implementation of the corrective action. This follow-up must be limited to inspection of the corrective action.

A very useful technique in tracking action on audit results is to issue periodic audit status reports. These should identify the status of each finding, the target dates for responses and corrective action, and the overall status of the audit.

When all findings have been closed, a letter or memo should formally close the audit. This is basic courtesy as well as good business practice. In the case of corrective actions that may be deferred for long periods, or where their completion cannot be determined without a follow-up audit, the individual audit should be closed and follow-up provided by other means, such as the audit status report or commitment control system. Finally, all corrective action should be examined at the next regularly scheduled audit of that area.

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